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EXAMINER	
MUTSCHLER, BRIAN L	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,909	JALALI ET AL.	
	Examiner	Art Unit	
	Brian L. Mutschler	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-147* is/are pending in the application.

4a) Of the above claim(s) *51-147* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 November 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20010228; 20021209*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-50, in Paper No. 20040329 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 51-147 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Comments

2. The Examiner wishes to note that in claims 41-43, it appears that the numbers recited in the claims do not match the claim language of similar claims 38-40. Claim 41 seems to be based on an array of 96 microstructures, which would suggest a total of 96 sets of first and second electrodes, as opposed to the claimed 192 sets of first and second electrodes. The current language suggests the presence of at least 384 electrodes, which does not appear to be in agreement with the two electrodes per microstructure, as described in the disclosure. There is nothing objectionable or indefinite about the current claim language since the claims 41-43 depend from claim 37, which does not disclose the number of arrayed microstructures.

Drawings

3. The drawings are objected to because they do not include reference signs identifying the various elements of the invention. As stated in 37 CFR 1.74, "When

there are drawings, there shall be a brief description of the several views of the drawings and the detailed description of the invention shall refer to the different views by specifying the numbers of the figures and to the different parts by use of reference letters or numerals (preferably the latter)." Figures 1-3, 4b, and 7-10 are lacking identifying reference signs. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure is objected to because of the following informalities:

   a. On page 7 at line 11, please change "masterfabricated" to --master fabricated--.

   b. On page 12 at line 18, please insert a period (".") after "layer" and before "Alternatively".

   c. On page 13 at line 18, please change "place" to --placed--.

   Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-5, 12-14, 16, 20, 25, 49, and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey et al. (U.S. Pat. No. 6,056,859) in view of Ramsey (U.S. Pat. No. 6,001,229), herein referred to as US '859 and US '229, respectively.

Regarding claim 1, US '859 discloses a system for separating molecules comprising a microstructure plate **10**, having a plurality of interconnected channels and structures (fig. 1). The structures include a plurality of reservoirs **20, 22, 24, 26**, including a sample accepting section, and electric fields are applied to move the material (col. 2, lines 39-65). The structures also include a capture section comprising a capture matrix (DNA probes) affixed to the surface of channel **16** (col. 3, lines 8-18). The system is made of a substrate **12** and a sealing (cover) plate **14** that is permanently bonded to the substrate (col. 2, lines 39-45). One reservoir **26** is held at a lower potential than the other reservoirs (col. 3, lines 20-34). US '859 incorporates by reference copending Application No. 08/283,769, which has issued as US '229.

Regarding claims 2 and 3, the reservoirs are open to the exterior of the system (col. 2, lines 40-65).

Regarding claim 12, the substrate **12** and the cover plate **14** are both transparent to light (col. 2, lines 40-46).

Regarding claim 13, the capture matrix comprises a material having the ability to covalently or non-covalently bind the molecule of interest (col. 3, lines 8-50).

Regarding claim 14, the capture matrix is positioned on the surface of the channel so that the molecule of interests passes tangentially to the capture matrix (figs. 2A and 2B).

Regarding claim 16, the capture matrix comprises DNA probes that bind the target molecule specifically (col. 3, lines 8-50).

Regarding claim 20, the capture matrix impedes the movement of the molecule of interest by binding it (col. 3, lines 8-50).

Regarding claim 25, the channels connecting the sections lie in a planar configuration (fig. 1).

The system of US '859 differs from the instant invention because US '859 does not expressly disclose the following:

a. The system comprises an electrode assembly having at least one first electrode and at least one second electrode, wherein each are disposed in separate sections, as recited in claim 1.

b. The opening in the sealing plate aligns with at least one electrode section, as recited in claim 4.

c. Each electrode of the electrode assembly extends through the at least one opening in the sealing plate towards the electrode section, as recited in claim 5.

d. Each pair of first and second electrodes is controlled individually, as recited in claim 49.

e. All first electrodes and all second electrodes are controlled together, as recited in claim 50.

Regarding claims 1, 4, 5, 49, and 50, US '229 discloses a system for separating charged molecules, wherein the flow of the charged molecules is controlled using a

plurality of electrodes **38, 40, 42, 44** that are inserted in the open ends of reservoirs **30, 32, 34, 36** (fig. 1; col. 4, lines 25-41). The electrodes are controlled by a voltage controller **140**, which controls each electrode individually (fig. 20). Since the system only contains one separation assembly, all of the first electrodes and second electrodes are controlled together.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system of US '859 to use the electrodes and electrode controller of US '229 because US '859 specifically teaches the use of the electrokinetic system of US '229.

7. Claims 1-5, 12, 13, 15-17, 20-23, 25, and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ullman et al. (U.S. Pat. No. 6,103,537) in view of JP 11-311616 A, herein referred to as JP '616.

Regarding claim 1, Ullman et al. teach a system for separating charged molecules comprising microfluidic plate **100** having a plurality of interconnected sections (reservoirs) and channels (fig. 1). The sections include a sample accepting section **104** and a capture section **125** (fig. 1; col. 25, line 50 to col. 26, line 54). The capture section contains a capture matrix (receptor-beads). Ullman et al. further disclose that transport occurs via electrokinetic means (col. 26, lines 23-28).

Regarding claim 12, since Ullman et al. teach that detection occurs within the system **100** by fluorescence, the plate must be transparent to light (col. 26, lines 46-54).

Regarding claims 13 and 16, Ullman et al. teach that the capture matrix may specifically bind the molecule of interest (col. 8, lines 27-63; col. 13, line 29 to col. 14, line 15; col. 26, lines 4-54).

Regarding claims 15 and 23, the molecule of interest passes orthogonal to the surface of the capture matrix (immobilized receptor-beads) (col. 26, lines 4-54).

Regarding claim 17, the capture matrix includes affinity binding materials such as antibodies, avidin, or streptavidin (col. 8, lines 27-63; col. 26, lines 4-54; col. 27, lines 25-38).

Regarding claim 20, the capture matrix impeded the movement of the molecules (col. 26, lines 29-45).

Regarding claims 21 and 22, the capture may comprise a material selected from cellulous and hydrogels, including agarose, polyacrylamide, and homopolymers and copolymers of derivatives of methacrylate and acrylate (col. 13, line 29 to col. 14, line 15).

Regarding claim 25, the channels lie in a planar configuration (fig. 1).

The system of Ullman et al. differs from the instant invention because Ullman et al. does not disclose the following:

a. The microstructures in the plate are formed by at least two layers of material, wherein at least one layer is a sealing plate layer, as recited in claim 1.

b. The system comprises at least one first electrode section and at least on second electrode section, and an electrode assembly having electrodes associated with each electrode section, as recited in claim 1.

c. The sealing plate comprises at least one opening to the exterior, as recited in claim 2.

d. The opening aligns with at least one sample accepting section, as recited in claim 3.

e. The opening aligns with at least one electrode section, as recited in claim 4.

f. Each electrode extends through at least one opening in the sealing plate toward the electrode section, as recited in claim 5.

g. The electrode assembly is integrated within the material of the microstructure plate, as recited in claim 44.

h. The electrode assembly is embedded within the sealing plate, as recited in claim 45.

i. The electrode assembly is a printed circuit on the sealing plate, as recited in claim 46.

j. The electrode assembly is held between two layers of the microstructure plate, as recited in claim 47.

k. The electrode assembly comprises an electrode support formed from a rigid or semi-rigid material and the electrodes are fixedly held on or within the electrode support plate, as recited in claim 48.

Regarding claims 1-5, JP '616 teaches a microfluidic device having a transparent plate structure with a substrate **5** and a sealing plate **3**, which encloses the channels **7** (figs. 1 and 4). Additionally, JP teaches the use of an electrode assembly having electrodes **9, 21, 53** that extend through an opening of the sealing plate **3** to contact the electrode sections (figs. 2 and 4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the plate of Ullman et al. to use a sealing plate having openings as taught by JP '616 because a sealing plate with openings prevents evaporation of the solution within the channels and the openings allow access to the sample inlets and to provide an electrical connection.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have further modified the electrokinetic means of Ullman et al. to use a plurality of electrodes passing through the openings of the plate as taught by JP '616 because electrodes provide an efficient and controllable means for providing the electrokinetic transport desired in the system of Ullman et al.

Regarding claims 44-48, JP '616 teaches several alternative electrode assemblies for use with the system (figs. 2 and 4). With regard to claims 44-47, JP '616 teaches an electrode assembly **21** deposited directly on the sealing plate and held between the sealing plate **3** and connecting means **23** (fig. 2). With regard to claim 48, JP '616 teaches an electrode assembly mounted on a semi-rigid (silicon rubber) support **49** having a plurality of electrodes **53** embedded within the support (fig. 4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the electrokinetic means of Ullman et al. to use any of the electrode assemblies taught by JP '616 because each assembly provides an adequate means to provide electrokinetic transport to the solution contained within the microfluidic channels.

8. Claims 1-13, 15-29, 33-35, and 44-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swedberg et al. (U.S. Pat. No. Re. 36,350) in view of JP 11-311616 A.

Regarding claim 1, Swedberg et al. disclose a system for electrophoretic or electrochromatographic separations comprising a plurality of plates, including a sealing plate layer, and a plurality of channels and sections (figs. 7B, 8A, and 15). An exemplary device, as shown in Figure 15, comprises a plurality of access ports **222, 224, 226** connected by channels (fig. 15). A plurality of capture regions **214, 216, 218, 220** are disposed between access ports and interconnected by the channels (fig. 15; col. 27, line 26 to col. 29, line 25). The capture regions contain a capture matrix to capture the molecule of interest (col. 27, lines 46-64). Sample flow is driven by motive means, which includes an electric potential, that access the sample through the access ports (col. 11, lines 62-67; col. 28, lines 14-20).

Regarding claims 2, 3, and 6, the sealing plate has at least one opening to the exterior that aligns with the various regions of the channels and access ports (figs. 7A, 7B, 8A, and 8B).

Regarding claims 7 and 8, the system comprises multiple layers that have openings to the exterior align with access ports (figs. 7A, 7B, 8A, and 8B).

Regarding claim 11, the system comprises a plurality of capture regions **214, 216, 218, 220** arranged in series and separated by one another by access ports (fig. 15).

Regarding claim 12, the system is made of transparent materials (col. 9, line 64 to col. 10, line 7).

Regarding claim 13, the capture matrix may comprise a material capable of covalently or non-covalently binding the molecule of interest (col. 27, lines 46-64).

Regarding claim 15, the capture matrix is positioned such that the molecule of interest passes through the capture region orthogonal to the surface of the capture matrix (fig. 15).

Regarding claims 16 and 17, the capture matrix may comprise an antibody or other specifically binding material (col. 27, lines 46-64).

Regarding claims 18 and 19, the capture matrix may comprise a material that binds the molecule of interest non-specifically, such as an anionic or cationic exchange medium (col. 27, lines 46-64).

Regarding claims 20 and 23, the capture matrix impedes the movement of the molecule of interest, which passes through the capture region orthogonal to the surface of the capture matrix (fig. 15; col. 27, lines 46-64; col. 28, line 64 to col. 29, line 25).

Regarding claims 21 and 22, the capture matrix may comprise materials such as nylon, cellulose, and hydrogels including polyacrylamide, agarose, or others (col. 27, lines 35-45).

Regarding claim 24, the channels lie in a three-dimensional configuration (figs. 6, 9, and 16B).

Regarding claim 25, the channels are substantially planar (figs. 7A and 8A).

Regarding claims 26-29, Swedberg et al. disclose a variety of embodiments comprising different configurations (figs. 1-16). All systems comprise a plurality of layers having voids defining channels and sections (figs. 1-16). The channels may be defined by voids in a single layer (e.g., fig. 1), or the channels may be formed by voids lying in multiple layers (e.g., figs. 10-14). The capture matrix is held between two layers of the system (col. 26, lines 23-44).

Regarding claims 33-35, the channels within the system have a diameter ranging from 5-200 μm, which corresponds to a cross-sectional area of ~20-30,000 μm^2 (col. 21, lines 31-53).

The system of Swedberg et al. differs from the instant invention because Swedberg et al. do not disclose the following:

a. The system comprises at least one first electrode section and at least on second electrode section, and an electrode assembly having electrodes associated with each electrode section, as recited in claim 1.

b. The opening of the sealing plate aligns with at least one electrode section, as recited in claim 4.

c. Each electrode extends through at least one opening in the sealing plate towards the electrode section, as recited in claim 5.

d. The opening of the non-sealing plate aligns with at least one electrode section, as recited in claim 8.

e. Each electrode extends through at least one opening in the non-sealing plate layer towards the electrode section, as recited in claim 10.

f. The electrode assembly is integrated within the material of the microstructure plate, as recited in claim 44.

g. The electrode assembly is embedded within the sealing plate, as recited in claim 45.

h. The electrode assembly is a printed circuit on the sealing plate, as recited in claim 46.

i. The electrode assembly is held between two layers of the microstructure plate, as recited in claim 47.

j. The electrode assembly comprises an electrode support formed from a rigid or semi-rigid material and the electrodes are fixedly held on or within the electrode support plate, as recited in claim 48.

Regarding claims 1, 4, 5, 9 and 10, JP '616 teaches a microfluidic device having a transparent plate structure with a substrate **5** and a sealing plate **3**, which encloses the channels **7** (figs. 1 and 4). Additionally, JP teaches the use of an electrode assembly having electrodes **9, 21, 53** that extend through an opening of the sealing plate **3** to contact the electrode sections (figs. 2 and 4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have further modified the electrokinetic means of Swedberg et al. to use a plurality of electrodes passing through the openings of the plate as taught by JP '616 because electrodes provide an efficient and controllable means for providing the electric potential desired in the system of Swedberg et al.

Regarding claims 44-48, JP '616 teaches several alternative electrode assemblies for use with the system (figs. 2 and 4). With regard to claims 44-47, JP '616 teaches an electrode assembly **21** deposited directly on the sealing plate and held between the sealing plate **3** and connecting means **23** (fig. 2). With regard to claim 48, JP '616 teaches an electrode assembly mounted on a semi-rigid (silicon rubber) support **49** having a plurality of electrodes **53** embedded within the support (fig. 4).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the electrokinetic means of Swedberg et al. to use any of the electrode assemblies taught by JP '616 because each assembly provides an adequate means to provide an electric potential to the solution contained within the microfluidic channels.

9. Claims 24 and 26-32 rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey et al. (U.S. Pat. No. 6,056,859) in view of Ramsey (U.S. Pat. No. 6,001,229), as applied above to claims 1-5, 12-14, 16, 20, 25, 49, and 50, and further in view of Chow (U.S. Pat. No. 6,167,910).

US '859 and US '229 describe a system having the limitations recited in claims 1-5, 12-14, 16, 20, 25, 49, and 50, as explained above in section 6.

Regarding claims 26-29, US '829 discloses the use of two layers having voids that define the channels, and the voids defining the channels are disposed on a single layer (fig. 1). The capture matrix is contained between the cover plate and the substrate (col. 3, lines 8-18).

Regarding claims 30-32, US '859 discloses that the substrate and cover plate may be made of glass, quartz, silicon, or organic polymeric material (col. 5, lines 15-17).

The system described by US '859 and US '229 differs from the instant invention because they do not disclose the following:

a. At least two channels lie in a three-dimensional configuration, as recited in claim 24.

b. The plate is comprised of more than two layers of material that comprise a plurality of voids defining the sections and channels, as recited in claim 26.

c. The voids defining the channels lie within more than one layer, as recited in claim 28.

d. At least one layer is formed from a self-sealing material, as recited in claim 30.

e. The self-sealing material is polydimethylsiloxane (PDMS), as recited in claim 31.

f. At least one layer is formed from polytetrafluoroethylene, as recited in claim 32.

Regarding claims 24, 26, and 28, Chow discloses a microfluidic system comprising a three-dimensional arrangement of channels formed by voids in a plurality of layers (fig. 1A). The three-dimensional arrangement allows for further reduction of microfluidic device size (col. 1, lines 41-45).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system described by US '859 and US '229 to use a three-dimensional arrangement of channels fabricated in a plurality of layers as taught by Chow because the three-dimensional arrangement allows for further reduction in the size of microfluidic devices.

Regarding claims 30-32, Chow teaches that microfluidic devices are preferably made from PDMS or polytetrafluoroethylene because such materials are easily manufactured at a low cost (col. 4, lines 40-59).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the polymer material used for the layers in the system described by US '859 and US '229 to use PDMS or polytetrafluoroethylene as taught by Chow because such materials can be easily manufactured at a low cost.

10. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swedberg et al. (U.S. Pat. No. Re. 36,350) in view of JP 11-311616 A, as applied above

to claims 1-13, 15-29, 33-35, and 44-48, and further in view of Chow (U.S. Pat. No. 6,167,910).

Swedberg et al. and JP '616 describe a system having the limitations recited in claims 1-13, 15-29, 33-35, and 44-48 of the instant invention, as explained above in section 8. Swedberg et al. further discloses that the system may be made from materials comprising polymers (col. 7, lines 55-52).

The system described by Swedberg et al. and JP '616 differs from the instant invention because they do not disclose the following:

a. At least one layer is formed from a self-sealing material, as recited in claim 30.

b. The self-sealing material is polydimethylsiloxane (PDMS), as recited in claim 31.

c. At least one layer is formed from polytetrafluoroethylene, as recited in claim 32.

Regarding claims 30-32, Chow teaches that microfluidic devices are preferably made from PDMS or polytetrafluoroethylene because such materials are easily manufactured at a low cost (col. 4, lines 40-59).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the polymer material used for the layers in the system described by Swedberg et al. and JP '616 to use PDMS or polytetrafluoroethylene as taught by Chow because such materials can be easily manufactured at a low cost.

11. Claims 33-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramsey et al. (U.S. Pat. No. 6,056,859) in view of Ramsey (U.S. Pat. No. 6,001,229), as applied above to claims 1-5, 12-14, 16, 20, 25, 49, and 50, and further in view of Bjornson et al. (U.S. Pat. No. 6,103,199).

US '859 and US '229 describe a system having the limitations recited in claims 1-5, 12-14, 16, 20, 25, 49, and 50, as explained above in section 6.

The system described by US '859 and US '229 differs from the instant invention because they do not disclose the following:

a. The channels have a cross-sectional area between 10,000 and 9,000,000 μm^2, as recited in claim 33.

b. The channels have a cross-sectional area between 10,000 and 250,000 μm^2, as recited in claim 34.

c. The channels have a cross-sectional area between 25,000 and 250,000 μm^2, as recited in claim 35.

d. The plate is approximately 8.5 cm by 11 cm, as recited in claim 36.

e. The plate comprises a plurality of rectangularly arrayed microstructures, as recited in claim 37.

f. The plate comprises 96 rectangularly arrayed microstructures, as recited in claim 38.

g. The plate comprises 384 rectangularly arrayed microstructures, as recited in claim 39.

h. The plate comprises 1536 rectangularly arrayed microstructures, as recited in claim 40.

i. The electrode assembly comprises 192 regularly arrayed sets of first and second electrodes, as recited in claim 41.

j. The electrode assembly comprises 768 regularly arrayed sets of first and second electrodes, as recited in claim 42.

k. The electrode assembly comprises 3072 regularly arrayed sets of first and second electrodes, as recited in claim 43.

Regarding claims 33-35, Bjornson et al. disclose a microfluidic device comprising channels having an inside diameter from 1 μm to 500 μm, which corresponds to a cross-sectional area of ~0.75 μm^2 to ~200,000 μm^2 (col. 11, lines 26-34).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the channels described in the device of US '859 and US '229 to use channels with cross-sectional area within the claimed range as taught by Bjornson et al. because such cross-sectional areas proved for capillary flow.

Regarding claims 36-43, Bjornson et al. disclose a microfluidic system comprising a plurality arrayed microstructures (figs. 5 and 6). The size of the system is based on the standard 96 well microtiter plate because it is a standardized format used in many applications (col. 3, lines 27-43). The standard microtiter plate has dimensions of approximately 8.5 cm by 11 cm. Bjornson et al. further disclose that the system corresponds to plates having 96, 192, 384, or 1536 wells, and that the array may

comprise any number of separate microstructures (networks) in multiples of 96 (col. 11, lines 41-45; col. 22, lines 32-42).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system described by US '859 and US '229 to use a rectangular 8.5 cm by 11 cm format having an array of 96, 384, or 1536 microstructures as taught by Bjornson et al. because using a standardized size allows for efficient automation using existing equipment and a plurality of microstructures allows for the simultaneous analysis of many samples at once.

12. Claims 33-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ullman et al. (U.S. Pat. No. 6,103,537) in view of JP 11-311616 A, as applied above to claims 1-5, 12, 13, 15-17, 20-23, 25, and 44-48, and further in view of Bjornson et al. (U.S. Pat. No. 6,103,199).

Ullman et al. and JP '616 describe a system having the limitations recited in claims 1-5, 12, 13, 15-17, 20-23, 25, and 44-48, as explained above in section 7.

The system described by Ullman et al. and JP '616 differs from the instant invention because they do not disclose the following:

a. The channels have a cross-sectional area between 10,000 and 9,000,000 μm^2, as recited in claim 33.

b. The channels have a cross-sectional area between 10,000 and 250,000 μm^2, as recited in claim 34.

c. The channels have a cross-sectional area between 25,000 and 250,000 μm^2, as recited in claim 35.

d. The plate is approximately 8.5 cm by 11 cm, as recited in claim 36.

e. The plate comprises a plurality of rectangularly arrayed microstructures, as recited in claim 37.

f. The plate comprises 96 rectangularly arrayed microstructures, as recited in claim 38.

g. The plate comprises 384 rectangularly arrayed microstructures, as recited in claim 39.

h. The plate comprises 1536 rectangularly arrayed microstructures, as recited in claim 40.

i. The electrode assembly comprises 192 regularly arrayed sets of first and second electrodes, as recited in claim 41.

j. The electrode assembly comprises 768 regularly arrayed sets of first and second electrodes, as recited in claim 42.

k. The electrode assembly comprises 3072 regularly arrayed sets of first and second electrodes, as recited in claim 43.

Regarding claims 33-35, Bjornson et al. disclose a microfluidic device comprising channels having an inside diameter from 1 μm to 500 μm, which corresponds to a cross-sectional area of ~0.75 μm^2 to ~200,000 μm^2 (col. 11, lines 26-34).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the channels described in the device of Ullman et

al. and JP '616 to use channels with cross-sectional area within the claimed range as taught by Bjornson et al. because such cross-sectional areas proved for capillary flow.

Regarding claims 36-43, Bjornson et al. disclose a microfluidic system comprising a plurality arrayed microstructures (figs. 5 and 6). The size of the system is based on the standard 96 well microtiter plate because it is a standardized format used in many applications (col. 3, lines 27-43). The standard microtiter plate has dimensions of approximately 8.5 cm by 11 cm. Bjornson et al. further disclose that the system corresponds to plates having 96, 192, 384, or 1536 wells, and that the array may comprise any number of separate microstructures (networks) in multiples of 96 (col. 11, lines 41-45; col. 22, lines 32-42).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system described by Ullman et al. and JP '616 to use a rectangular 8.5 cm by 11 cm format having an array of 96, 384, or 1536 microstructures as taught by Bjornson et al. because using a standardized size allows for efficient automation using existing equipment and a plurality of microstructures allows for the simultaneous analysis of many samples at once.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hu et al. (U.S. Pat. No. 6,623,860) disclose an arrayed

microfluidic device having a plurality of layers forming a three-dimensional arrangement of channels.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian L. Mutschler whose telephone number is (571) 272-1341. The examiner can normally be reached on Monday-Friday from 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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